THE OBJECTION TO THE SPECIFICATION AND THE REJECTION OF CLAIMS 31-41 UNDER 35 U.S.C. 112, FIRST PARAGRAPH

Claims 31-41 are rejected as allegedly not enabled. The claims refer to particular known genes, but the genes are not described by nucleotide sequence. Rather, the genes are described by names. The specification further provides accession numbers for each of the genes in a database of sequences maintained by the U.S. government. The Office Action asserts that this is an attempt to incorporate by reference material that is essential to the practice of the claimed invention. Moreover, it asserts that this is an improper incorporation by reference since the material is not contained in an issued U.S. patent. This rejection is respectfully traversed.

Claim 31 has been amended in the current amendment to recite names of genes, rather than numbers referring to a figure. Thus there is no reference at all to anything outside of the claims, let alone an improper reference or an improper incorporation by reference.

It is respectfully submitted that one of ordinary skill in the art would be able to practice the invention without recourse to undue experimentation. Each of the genes is known in the art, as evidenced by its accession number in a public database. The rejection fails to point out what aspect of the invention would require undue experimentation.

The claims are enabled because one of ordinary skill in the art could practice the invention without recourse to undue experimentation. Moreover, the claims contain no improper incorporation by reference of essential material because the claims contain no reference to other material. Withdrawal of this rejection is respectfully requested.

REJECTION OF CLAIMS 31-41 UNDER THE JUDICIALLY CREATED DOCTRINE OF DOUBLE PATENTING

Claims 31-41 are rejected as unpatentable over claims 1-24 of U.S. Patent No. 6,020,135. This rejection is respectfully traversed.

U.S. Patent No. 6,020,135 issued from application serial no. 09/049,025. During the prosecution of the reference application a restriction requirement was issued. Communication dated 12/21/98, attached. The restriction requirement designated claims 44-45 as claim group

IV. These claims were elected and issued in the 6,020,135 patent. The same restriction requirement designated claims 31-41 (currently under examination in the subject application) as claim group II. The Communication designated these claims as patentably distinct inventions. See page 2. Specifically, the Communication stated that "[i]nventions II and IV are drawn to two independent and distinct processes which have different goals, different intermediate steps and different end results." See page 3. Moreover, "they have acquired a separate status in the art as shown by their different classification." *Ibid.* Thus this rejection appears to be based on a conclusion which is directly opposite to that taken previously by the Patent Office in a parent application. Applicants relied on the restriction requirement in filing the subject divisional application.

35 U.S.C. 121 mandates that claims issuing from one of a restricted group of claims cannot be used to reject claims of another of the restricted group of claims in a divisional application. Nonetheless, that appears to be the basis for the current rejection. Thus this rejection appears to violate section 121.

Applicants request that the Patent Office reconsider the propriety of this rejection in view of the restriction requirement issued in the 6,020,135 patent. If the rejection is deemed improper, as applicants believe it is, it should be withdrawn.

Respectfully submitted,

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Dated: February 25, 2003

SAK AM/1

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/049,026	03/27/98	LEVINE	[illegible]

HM21/1221

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EXAMINER	
WILSON, A	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 12/21/98

RECEIVED
DEC 29 1998
BANNER & WITCOFF LTD.

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

DOCKETED
DEC 29 1998
Restriction Req Due 21JA99
Last Day 21JE99

COPY

Office Action Summary

Application No.	Applicant(s)
09/049,025	Levine et al.
Examiner	**Group Art Unit**
Ethan Whisenant	1634

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-66* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-66* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

ELECTION/RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-30, 64-66, drawn to a method of diagnosing cancer or determining p53 status in a sample suspected of being neoplastic, classified in Class 435, subclass 6 and/or subclass 7.1.

II. Claims 31-41, drawn to a method of evaluating the carcinogenicity of an agent, classified in Class 524, subclass 9.2.

III. Claims 42-43, drawn to a method of treating cancer, classified in Class 514, subclass 44.

IV. Claims 44-45, drawn to a method of screening drugs for utility as agents to treat cancer, classified in Class 524, subclass 9.2.

V. Claims 46-63, drawn to a set of olgonucleotide probes which hybridize to p53 regulated genes, classified in Class 536, subclasses 23.1 and 24.3.

2. The following explains why the groups above are patentably distinct inventions.

Inventions I and II are drawn to two independent and distinct processes which have different goals, different intermediate steps and different end results.

Inventions I and III are drawn to two independent and distinct processes which have different goals, different intermediate steps and different end results.

Inventions I and IV are drawn to two independent and distinct processes which have different goals, different intermediate steps and different end results.

Inventions I and V are related as a process and product. The product in this case (Invention V), can be used in the process of Invention I, however, it may also be used in a materially different

process for using the product. For example, the oligonucleotides of Group V may be used as molecular weight markers in gel electrophoresis.

Inventions II and III are drawn to two independent and distinct processes which have different goals, different intermediate steps and different end results.

Inventions II and IV are drawn to two independent and distinct processes which have different goals, different intermediate steps and different end results.

Inventions II and V are related as a process and product. The product in this case (Invention V), can be used in the process of Invention II, however, it may also be used in a materially different process for using the product. For example, the oligonucleotides of Group V may be used as molecular weight markers in gel electrophoresis.

Inventions III and IV are drawn to two independent and distinct processes which have different goals, different intermediate steps and different end results.

Inventions III and V are related as a process and product. The product in this case (Invention V), can be used in the process of Invention III, however, it may also be used in a materially different process for using the product. For example, the oligonucleotides of Group V may be used as molecular weight markers in gel electrophoresis.

Inventions IV and V are related as a process and product. The product in this case (Invention V), can be used in the process of Invention IV, however, it may also be used in a materially different process for using the product. For example, the oligonucleotides of Group V may be used as molecular weight markers in gel electrophoresis.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. A telephone call was made to Sarah Kagan on 8 DEC 98 to request an oral election to the above restriction requirement, but did not result in an election.

The applicant is advised that the response to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Group is (703) 305-3014. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.

ECW

Ethan Whisenant, Ph.D.
Patent Examiner

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600
12/19/98

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